[No audible response.]

MS. HALL: Okay, so we'll move ahead.

[Discussion off the record.]

MS. HALL: Number 17, Peter Lurie, would you like to take a seat up here? And then Speaker Number 19, Ami Zota, please take a seat in the on-deck chairs. Thank you.

MR. STANKO: Thank you. My name is Joseph Stanko, S-T-A-N-K-O. Thank you for the opportunity to address EPA's proposal entitled, "Strengthening Transparency in Regulatory Science." My name is Joseph Stanko, and I am counsel to the NAAQS Implementation Coalition.

The Coalition is comprised of trade associations, companies, and other entities who confront challenges in permitting and operating manufacturing and other facilities under increasingly stringent National Ambient Air Quality Standards.

Our members --

MS. ORME-ZAVALETA: If we could ask you to move the microphone a little bit more in front.

MR. STANKO: Sure.

MS. ORME-ZAVALETA: No, the other way. There you go.

MR. STANKO: All right.

MS. ORME-ZAVALETA: Thank you.

MR. STANKO: Our members, and the companies they represent have a proven record of working with states and regional EPA offices on implementing emissions reduction strategies to attain NAAQS.

However, increasingly more stringent NAAQS have caused demonstration requirements for Clean Air Act permits to exceed the limits of current tools and policies for NAAQS implementation. This makes it increasingly more difficult for companies to attain the approvals needed for new state of the art projects that create jobs and bring much-needed tax revenue to local communities.

Without a transparent NAAQS process, underlying studies lack robust external review, leading to standards that may not provide

objective public benefit. In certain cases, increasingly stringent standards have pushed NAAQS to concentrations at or near background levels, beyond the feasible limits of implementation. While inaccurate assumptions in both setting and implementing NAAQS could be more readily absorbed under prior less stringent NAAQS levels, recent more stringent standards have eroded such tolerances.

Addressing this new reality starts with an inherently forward-looking NAAQS review process that assesses science and policy in a rigorous and holistic manner. The transparency proposal fosters such an open-source approach to pivotal regulatory science, one that enables the public to more meaningfully comment on the science underlying NAAQS review. This can foster a more effective NAAQS implementation that still meets the Clean Air Act's mandate to protect public health.

While we support the principles behind the transparency proposal, its sound policy goals

should be balanced with legal and ethical obligations to protect private, sensitive, and confidential information. As the transparency proposal is implemented, efforts must be made to address protected health information under the Health Insurance Portability and Accountability Act, or HIPAA.

Disclosure limitations also exist for proprietary information and trade secrets. We agree with EPA that dose response data and models should be exempt from public review as necessary to protect private, sensitive, and confidential information. However, we believe that EPA can protect such information while still seeking maximum possible transparency.

As the transparency proposal notes, many generally acceptable techniques exist to deidentify personally identifiable information. Where such deidentification is not possible, EPA could facilitate review of sensitive data sets by a diverse group of experts subject to HIPAA compliant nondisclosure agreements.

If all other options to expand review have been exhausted, EPA could decide that a study could not be subject to outside review and verification, and consider the study accordingly without excluding it from a rulemaking proceeding.

Administrations -- administrators pardon me, have regularly taken similar methodological considerations into account when assessing studies in past NAAQS reviews. EPA could further balance transparency and privacy by appropriately tailoring the transparency proposal according to the type and scope of the regulatory decision involved. For this reason, we agree with EPA that the transparency proposal should be limited to pivotal regulatory science that is involved in significant regulatory actions that result in substantial costs.

To that end we note that because Clean Air Act regulations have accounted for the vast majority of costs and benefits cited in rules over the last decade across the entire federal government, such regulations are particularly well

suited for the transparency proposal's high standard of robustness.

As this process moves forward, we encourage EPA to further detail how the transparency proposal will protect private, sensitive, and confidential information, be it personally identifiable or proprietary information, trade secrets, or other similar information. To that end, EPA should explicitly state that any final regulations arising from the transparency proposal do not support or assert authorization under the law to disclose such currently protected information, and that any claim to do so must be independently based on a statutory grant of authority from congress.

In conclusion, the transparency proposal would increase replicability and verification in the scientific process, thereby testing critical methodological assumptions and mitigating biases in key studies upon which the Agency relies in developing regulations. It recognizes that transparency can go beyond simply maximizing

disclosure to better contextualizing studies through replicability and verification.

In doing so, the public can more meaningfully take part in EPA notice and comment rulemaking processes. As EPA advances the transparency proposal, it can and should implement these sound policy goals in concert with obligations to protect private, sensitive, and confidential information.

The NAAQS Implementation Coalition appreciates EPA's efforts on the transparency proposal, as well as the opportunity to present its view on the topic.

MS. ORME-ZAVALETA: Thank you.

MR. LURIE: Hear me? Good morning. My name is Dr. Peter Lurie. I'm a physician, an epidemiologist, and now the President for Center for Science in the Public Interest. We are an independent science-based health advocacy organization with over 500,000 members.

Before I joined CSPI, I served at the FDA as an associate commissioner and in fact, for

several years I led the Agency's transparency initiative. Over the course of my career I've authored close to a dozen academic articles on the topic of transparency, and nobody ever asked me for the underlying data for any of those studies.

We at CSPI are firm advocates of scientific transparency and have had a number of projects along those lines over the years. But EPA's proposed rule is not about transparency or strengthening science. Instead, it is a wolf of pro-industry bias hiding in the sheep's clothing of transparency in science. Proposal should be withdrawn.

Transparency is not about restricting the use of sound science, as this proposal would do. Suddenly, the more transparent a government agency can be about the nature and limitations of the data underlying a decision, the better. But the failure to meet some abruptly and arbitrarily elevated standard for disclosure cannot and should not be the grounds for the summary exclusion of data that were rigorously gathered and reported.

The surest tests of any scientific transparency policy are two. One, was it generated in a transparent fashion? And two, will it actually promote the transparent rigorous science-based decision-making that it claims to? This proposal fails on both counts. Let's start with the procedural matter.

This proposal violates fundamental tenents of transparency rulemaking. EPA failed to consult with relevant stakeholders, such as science, research, or health professional associations, did not consult with other federal agencies who would be affected by this, and did not even make the proposed rule available to its own Scientific Advisory Board for review.

In addition, the proposal lacks critical citations and documentation, or even an adequate justification for why it was proposed. Rather than furnishing the evidentiary support required for administrative action, the Agency has merely adopted a legislative initiative that failed to (indiscernible) despite support from the energy,

chemical, manufacturing, and other key industries.

Moreover, despite its professed (indiscernible) to cost effectiveness in rulemaking, the proposed rule provides no cost-effectiveness analysis whatsoever. It simply blithely asserts that, quote, "EPA believes the benefits of this proposed rule justify the costs." I wish we could have gotten away with that at FDA.

But the rule would be costly indeed. Analysis of an earlier version of the legislation predicted costs of $250 million over the next few years. But even more important, the proposal does not meet its purported scientific goals and will instead undermine the scientific basis for decision-making at EPA.

Since its inception, EPA has developed rules with demonstrable efficacy in protecting the public by relying in large part upon the kinds of data that EPA would now preclude from consideration. Some of EPA's greatest public health accomplishments, such as eliminating lead and gasoline, classifying second-hand smoke as a

cause of cancer were based on the kinds of data that would be discarded under the proposal. Such data are widely used in rulemaking proceedings by other U.S. government agencies and around the world. And I can say, at FDA, we would not have had the rules that we ultimately developed or proposed on mercury in fish, on arsenic in rice, on dental amalgam, or in sodium targets from a nutritional perspective. None of those could have been done if data of these kinds were eliminated.

In particular, it's also especially troubling that the proposal also opens the door to a reconsideration of past rules which would be utterly inappropriate under prevailing principles of administrative law. In fact, the proposal would have an effect opposite to its claimed purpose. It would address -- it would suppress important and relevant science conducted in large part by the best minds in academia and government, thereby unduly restricting the evidence available to EPA and potentially favoring data developed by industry.

Further evidence of the pro-industry orientation of this proposal is its discussion of the dose response function and the assault on linearity. Quite aside from the merits of that discussion, which I think are few, the real question is, what is this discussion doing in this proposal in the first place. It has nothing to do with transparency whatsoever, and it's simply there as a marker, in my view, of the pro-industry bias that this entire enterprise represents.

Let me close with a question with which EPA should have started. What exactly is the problem that this proposed rule seeks to fix? Where indeed is the study for which the lack of access to raw data resulted in misinterpretation or in the promulgation of an inappropriate regulatory standard?

To the contrary, the record is replete with studies that form the basis of health and life saving regulations that would now be precluded from use, and that might even provide a basis for the revocation of rules enacted in the

distant past. Thank you.

MS. HALL: Thank you. Would Speaker Number 18, Jamie Wells, and Speaker Number 19, Ami Zota, please come up to the speaker's table. And Speaker Number 20, Surbhi Sarang and Speaker Number 21, Laura Bloomer, please take a seat in the on-deck chairs. Thank you.

Please, quick reminder to speak into the mic and state your organization.

MS. WELLS: My name is Dr. Jamie Wells, J-A-M-I-E W-E-L-L-S, and I'm the Director of Medicine for the American Council on Science and Health, and I'm here on behalf of our president, Hank Campbell.

In the past, peer-reviewed journal publication ha been considered authoritative, but that has inherent weakness if they can't be replicated. Knowing the potential for error, and even misuse, replication is vital, but we recognize that that's not always possible. A safety valve for that is a higher level of scrutiny when it is not possible. Studies that

can't be replicated should at least make sense within the pattern of available data, which in the case of EPA will often include hundreds of other studies done according to federal guidelines.

However, there are also occasions where replication is not possible and new claims or outliers from the consensus of many other studies. And in those cases, they should still absolutely be used if EPA risk scientists, without breaking confidentiality, can obtain the additional information needed in order to conduct their own analysis.

EPA risk scientists are charged with protecting public health, and the American Council on Science and Health has argued since 1978 that the judgment over which epidemiology and/or toxicology data to use for risk or safety assessment should always include risk scientists. The public's interest is best served when science is replicable and consistent with other information.

On occasions, when studies cannot be

replicated, or when such studies are not consistent with other information, use of those studies depends on having access to the underlying data for independent analysis. When the underlying data are not provided, it is difficult to make a credible risk assessment, much less national rulemaking, as you know. So risk experts should be involved.

You should have received a more extensive written document as well.

MS. ORME-ZAVALETA: Thank you.

MS. ZOTA: I'm Dr. Ami Zota, that's A-M-I, last name Z-O-T-A. I am a health scientist and Professor of Environmental and Occupational Health at the George Washington University Milken Institute School of Public Health. I am also speaking as part of Project Tender. We are an alliance of scientists, health professionals, and advocates with expertise in protecting children from exposure to toxic chemicals that can contribute to neurodevelopmental problems, such as ADHD and learning disabilities.

I oppose EPA's proposed rule. The proposed rule prohibits the Agency from setting regulations that are support in part or whole that is for data that is publicly available for reanalysis or cannot be replicated.

Since the proposed rule is retroactive, it could lead to the dismantling of many important existing EPA regulations that safeguard our children and families -- children and families from toxic chemicals.

I would like to spend my time identifying some of the major problems with this rule that warrant consideration before the Agency moves forward. The scientific sources cited for the basis of this rule do not support the proposed rule. EPA did not consult with critical stakeholders in the development of this proposed rule, including scientists, health professionals, and affected communities.

EPA does not present any analysis of benefit-cost, children's environmental health risk, or environmental justice in support of the

rule which are required under executive orders 12291, 13045, and 12898. The terms, pivotal regulatory science, replication, reproducible, and research data are not defined or are problematic. The rule's requirements for specific types of defaults, test methods, dose response models, and/or analysis are not supported by current science.

The rule is counter to the mandates in the reformed Toxic Substances Control Act, or TSCA, to use the best available science and systematic reviews for chemical evaluations.

Data deidentification and masking techniques cannot ensure confidentiality and can degrade the accuracy of data for further analysis. The rule is inconsistent with medical ethics and existing legal requirements to ensure the privacy and/or confidentiality of human data.

For example, in many cases individuals' participant data cannot be made public because of confidential requirements legally mandated by institutional review boards and/or the Health

Insurance Portability and Accountability Act of 1996, or HIPAA.

In conclusion, EPA should withdraw this proposed rule immediately. EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at the federal government. Thank you.

MS. HALL: Thank you.

Would Speaker Number 20, Surbhi Sarang, and Speaker Number 21, Laura Bloomer, please come up to the speaker's table. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please take a seat in the on-deck chairs. Thank you.

Speakers, please remember to speak into the mic and state your organization.

MS. SARANG: My name is Surbhi Sarang, spelled S-U-R-B-H-I S-A-R-A-N-G, and I'm a legal fellow at the Environmental Defense Fund.

I appreciate this opportunity to provide public testimony on the proposal and hope that everyone who wises receives an opportunity to be

heard. We urge EPA to hold hearings in additional locations to allow affected Americans in other communities who cannot travel to be here today, an opportunity to provide input as well. I'm testifying here today to raise our serious concerns of the proposed rule and to ask that the EPA withdraw the proposed rule immediate.

Communities across America rely on EPA safeguards to protect their health and wellbeing. But this rule would greatly restrict the body of scientific information that EPA draws on when setting these safeguards. Instead of being informed by all available science, in many cases EPA would be forced to operate in the dark. By obliging EPA to disregard scientific research that would otherwise alert the Agency to taking strong protective actions, this rule endangers the health of all families and communities. Had this rule been place previously, we would likely currently be facing greater exposures to air pollutants, water contaminants and toxic chemicals.

In the proposal, EPA completely ignores

the practical effects of the proposed rule and how it fundamentally conflicts with EPA's mandate to use the best available science as it develops safeguards.

Agency decisions must be informed using the best available science. Public deserves nothing less when health and safety are on the line. This value is core to EPA's mission and should be placed at the forefront.

But the proposal takes an unsupported and unprecedented leap by suggesting that this mission allows EPA to only use science where the underlying data and models can be made and are made publicly available for independent validation. Much of the data underlying scientific studies concerning human health cannot be made publicly available for legitimate privacy and confidentiality reasons. In many cases, it is impossible even to redact information in a manner that allows independent validation while respecting privacy and confidentiality.

Thus, the proposal would seriously

restrict EPA's ability to use the best available science as it sets critical safeguards. Nor does EPA explain why such restrictions on the use of science are necessary. EPA does not point to any instance in which a failure to disclose data resulted in an EPA decision or standard that lacks scientific integrity.

EPA does not explain why other means of vetting that are used by the scientific community and that protect privacy and confidentiality, such as review by EPA's independent Science Advisory Board, peer review, and corroboration through independent studies are insufficient to ensure the integrity of the science EPA relies on. And EPA does not explain why it is appropriate for an agency tasked with basing its decisions on best available science to now discard otherwise valid science simply because a disclosure is not possible.

Indeed, courts that have examined the issue have made clear that it is entirely reasonable for EPA to rely on scientific studies

which data cannot be disclosed. While EPA states in the proposal that many organizations have endorsed data disclosure as a means to increasing transparency, the reality is the proposed rule completely departs from good scientific practice. None of the organizations EPA identifies in the proposed rule have endorsed the practice of disregarding studies where data disclosure is not possible, or that have been subjected to other means of validation, or suggested that regulatory agencies should exclude such studies when using science to inform regulatory actions.

To the contrary, organizations that are deeply committed to transparent science have come forward to stress that policies to promote transparency must be developed within the scientific community and to oppose the notion of disregarding otherwise valid science, simply because the underlying data cannot be disclosed.

Indeed, EPA's own Science Advisory Board, which it failed to consult before issuing this proposal, has raised concerns similar to those we

raise here, noting that EPA provided no analysis of the impact of losing the ability to run on these studies, and that there are other ways to assess the validity of studies without access to data. Not only did EPA skip over review by the Science Advisory Board, but then EPA allowed for only a 48 (indiscernible) review process for the proposal.

This hastened process seriously calls into question the validity of the proposal. The proposal would not even increase transparency. By allowing the administrator to grant exemptions based on vague and discretionary criteria, the proposal would allow EPA to selectively apply this disclosure policy with no public record of the decision or its basis. The risk that the rule will artificially restrict and distort the scientific basis for EPA's decisions is only heightened by its many gaps.

The proposal fails to explain critical details, such as what mechanisms would be used to make data public, what the cost of the Agency and

to researchers would be, and how the peer review provision would fit into EPA's existing peer review requirements. It is not even clear how EPA would determine that a given study is publicly available in a manner sufficient for independent validation. This underscores concerns that this proposal would undermine the integrity and transparency of EPA decisions rather than enhance them.

It is also important to note that this rule was posed under former Administrator Pruitt who actively obscured transparency goals by directing the removal of scientific information from EPA's websites, refusing to publicly release his full and accurate schedule, using secret e-mail addresses, and spending tax payer money in violation of federal laws.

While Pruitt is now gone, this proposal unfortunately suffers from the same disregard for scientific integrity and transparency that infused the former administrator's tenure.

We thus call on Acting Administrator

Wheeler to recognize the redeemably flawed basis for this proposed rule and withdraw it immediately.

MS. ORME-ZAVALETA: Thank you.

MS. BLOOMER: My name is Laura Bloomer, B-L-O-O-M-E-R, and I'm a student at Harvard Law School and the Kennedy School of Government. I am interning at EDF, Environment Defense Fund this summer. I am here testifying on my own behalf.

I am the daughter of two parents who grew up near auto industry towns in Michigan. My mom was born in Flint. Her parents, my grandparents, grew up in Flint and chose to raise their four children there.

Though I'm a proud Texan, as my family moved to Houston when I was in elementary school, most of my family continues to call Michigan home. The Flint water crisis was personal for us.

My aunt, a dental hygienist, volunteered and delivered water to Fling residents after the story broke. She understood the heart wrenching fear a mother would experience when she found out

her child had been drinking contaminated water. She understood the outrage of her home community when they found out that the government they trusted did not care enough to keep their drinking water safe. She understood what it might feel like to have a fundamental safeguard, like clean water, suddenly disappear.

But the water crisis in Flint did not disappear when it left the nightly headlines. Just last week, my mom went to her favorite hotdog shop in Flint and sent me a photo of a poster from the restaurant. It was an advertisement for healthcare, aimed at mothers of children who grew up drinking contaminated water. My mom was devastated.

And though the Flint water crisis is more salient and more visible than this proposed rule, the impacts are far too similar. For decades the EPA has relied on first-rate science to establish protections for our air and water, and most importantly for our public health.

It is because of these safeguards that I

have never experienced the type of pollution my mom describes from her childhood. It is because of incredible researchers and scientific discoveries that many of our communities will never experience a water crisis like Flint is still experiencing. It is because EPA regulates lead in our drinking water, and arsenic in our drinking water, and the many other contaminants that harm our most vulnerable populations that my friends and I grew up in a healthy environment.

It is because EPA has a responsibility to seek out and utilize the best available science at every step of the way, that the next generation of children will be protected from threats to their health as well.

Yet right now, in 2018, when our science has never been more advanced, and when EPA is considering revising the Lead and Copper Rule for drinking water, EPA would choose to voluntarily ignore the best available science. This proposed rule would severely limit the studies on which EPA could rely. It would threaten the enormous amount

that EPA and engaged citizens have accomplished, and it would hamstring any progress we hope to make in the future.

This rule isn't about transparency, and it was not developed with people like my family and me in mind. For the safety of all of us and for future generations, I respectfully ask that this rule be withdrawn. Had this rule been in place decades ago, more communities might be suffering from the same threats to public health that Flint is now facing. Many of EPA's drinking water standards rely on epidemiological studies. Often these studies last decades and follow hundreds, if not thousands of patients, collecting confidential health data, as well as other personal data, like the people's addresses, ages, and genders.

For most of these studies the underlying data cannot be made public, even in redacted form, without sacrificing the participants' privacy. These studies are monumental and state of the art. These are the studies that EPA should hope to rely

on, not the type of studies the EPA should shun. These are the studies that will guarantee that communities don't suffer from the devastating impacts of dirty water and polluted air. Studies like these establish the original limits for lead, and this research continues to essential today.

This proposed rule may seem abstract, but it is anything but that. And it is extremely significant. It will have far-reaching -- far-reaching impacts on the ability of EPA to protect all of us and our families. And it could affect our most important environmental safeguards. It is extremely personal, for my mom, for my family, and for me.

I am here today to ask you to withdraw this proposed rule and recommit to EPA's mission of protecting human health and the environment. Thank you for the opportunity to speak today.

MS. Hall: Thank you. Would Speaker Number 22, Ms. Nsedu Obot Witherspoon, and Speaker Number 23, Joanne Zurcher, please come up to the speaker's table. And Speaker Number 24, Michelle

Endo and Speaker Number 25, Jenny Xie, I think, please take a seat at the on-deck chairs.

[Substitution of panel members.]

MR. ROBBINS: Good morning. I'm Chris Robbins. I'm the Acting Deputy Assistant Administrative for Management in the Office of Research and Development.

MS. ORME-ZAVALETA: Good morning.

MR. ROBBINS: Thank you.

MS. DOA: Good morning. My name is Maria Doa , I am in the Office of Research and Development.

MS. WITHERSPOON: Good morning. I'm Nsedu Obot Witherspoon. I'm the Executive Director for the Children's Environmental Health Network. My name is spelled N-S-E-D-U O, B as in boy, O-T W-I-T-H-E-R-S-P-O-O-N.

For over 26 years, the Children's Environmental Health Network, also known as CEHN, has been a national voice committed to protecting all children from the harmful effects of environmental hazards, and to promoting a

healthier environment.

CEHN educates decision makers and advocates for evidence-based child protective policies. We also ensure that those who care for children, personally or professionally, have the information they need to take the steps to reduce children's exposures to harmful toxicants.

As the Executive Director, and on behalf of CEHN, I appreciate the opportunity to provide these comments on the EPA proposed rule, "Strengthening Transparency in Regulatory Science."

CEHN is strongly opposed to the rule and is concerned that it will adversely affect EPA's ability to use the best available science in decision-making, and negatively influence existing and future protections for children's health, such as clean air, clean water, and the prevention of toxic exposures.

The exposed rule sets transparency standards that are too rigid and impossible to meet. It requires that all data used in

rulemaking be publicly made available, and allows EPA to exclude data that relies on confidential patient information. Critical studies which have led to significant advancements in protective policies, for example from the NIEHS, EPA's Children's Environmental Health, and Disease Prevention Research Centers may very well be excluded.

The scientific research that EPA uses already undergoes a long-established transparent review process, and makes available the scientific studies it relies on to inform policy. Sometimes studies contain private medical data that legally can't and should not be made public. In those cases, independent review bodies have also examined the studies and weighed in on the research. No legitimate reason exists to exclude those studies and their critical important findings.

Health based research involves people and often the collection of private information. There are no systems in place to protect this

information. The federal government must continue to protect private information about patients, and not allow this information to be made public. Otherwise, patients will not participate in these important studies.

Further, redacting personal information actually sounds easy, however, it is cumbersome and quite costly. EPA will not likely have the resources to redact personal information resulting in exclusion of critical studies.

The proposed rule would restrict EPA's ability to set regulations informed by confidential data that cannot be replicated. This is of serious concern because for many older, long-standing landmark studies, the original data sets were either not maintained, or stored in out of date formats. These could be eliminated under this proposed rule.

The proposed rule could block the use of studies on the harmful impacts of toxic exposures and pollution. Studies which were instrumental in the Clean Air Act, the Safe Drinking Water Act,

and the -- excuse me, Food Quality Protection Act, among many others. We do request that you withdraw this proposal, "Strengthening Transparency and Regulatory Science." If the proposed rule is implemented, an inevitable consequence is that children that could have been protected from chemical exposures will lose those opportunities.

Irreversible damage to children in their growth and development, loss of intelligence, behavior modifications, and overall life achievement is the future ahead, and I would hope, not the legacy that this EPA would like to preserve. Thank you very much.

MR. ROBBINS: Thank you.

MS. ZURCHER: My name is Joanne Zurcher, J-O-A-N-N-E Z-U-R-C-H-E-R, and I'm representing the National Environmental Health Association.

Good morning. Thank you for the opportunity to speak to you on behalf of the environmental health professionals from across the country who've vigorously opposed the Censoring

science rule.

My name is Joanne Zurcher, and I am the Director of Government Affairs for the National Environmental Health Association, NEHA.

Environment health is profoundly local. Simply put, it's the cleanliness of the water from the kitchen faucets. It's the safety of the food we feed our families, our friends, and ourselves. It's the air the children breath during the 1,600 hours they spend inside their schools. It's the cleanliness of our community beaches that our families are spending the summer enjoying.

When things go well, environmental health is not on the front page of the New York Times, because environmental health professionals keep us safe every single day.

NEHA has over 7,000 members. Our members anticipate, recognize, evaluate, and control hazards that are likely to cause harm, serious illness, or even death to American families. Examples include lead, radon, legionella viruses, harmful algae blooms, PFOA, PFOS, Zika viruses,

and many other natural and man-made risks. Our members possess strong science and math backgrounds. They must take over 30 units of undergraduate math and science just to sit for our exam. They have the unique ability to work with clinical and nonclinical professionals. They know and work with the regulated community. They are credentialed members of the profession, and the NEHA credential is considered the gold standard.

EPA science is the foundation for informed decision-making for our members. Our members turn to the EPA for best practices. Our members rely on EPA research to promote their community's health.

Our communities see EPA as the shelter of scientific certainty in an era of uncertainty. Our members rely on EPA expertise, whether it's continuing -- excuse me, containing mercury spills in their homes, setting standards to keep toxic chemicals out of drinking water, or cleaning up super fund sites, just to name a few of the few activities we do together. EA professionals work

closely with the EPA every step of the way.

The EPA has administered successfully, the Clean Water Act, and the Clean Air Act, and these acts should be expanded based on scientific research. The EPA should not be working to undermine scientific research. Instead, this EPA should be working to provide running water to the 630,000 American families who do not have running water in their homes.

Let's be clear, this proposed rule undermines the EPA's mission to protect human health. Now is not the time to compromise health of our nation by casting a shadow of uncertainty on the integrity of the EPA -- of EPA's research.

EPA research is globally recognized as the foundation for informed decision-making that affects every person the plant. NEHA and it's 7,000 members are in every community and territory in the nation. Every EH professional relies on EPA research to ensure constituents meet human -- meet their human potential.

The current research system works, which

at once protects the identity of every research participant, while promoting the health of every American. Health research sometimes includes sensitive data from patients, such as medical history and geographic location, which must be continued to be private and protected. Crucial volunteers will cease to come forward for scientific research if their medical history and geographic information will be made public, thus putting critical scientific research at risk. Please do not destroy a national gem, our EPA research, because you, your family, and your community deserve no less than a fully functional research system that protects and identifies research subjects while promoting the health of the nation.

NEHA and the environmental health professionals from across the United States vigorously oppose the censoring scientific rule. Thank you for this opportunity to be heard on this important topic, and please remember, do no harm.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 24, Michelle Endo, and speaker Number 25, Jenny Xie, come up to the speaker's table. And Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, please take a seat at the speaker's -- well, at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. ENDO: My name is Michelle Endo, E-N-D-O, and I'm speaking in a personal capacity, but I'm an intern at the Environmental Defense Fund.

So my name is Michelle Endo, and I'm a second-year student at Georgetown Law. I'm also a legal intern at the Environmental Defense Fund here in Washington, D.C. I'm here today to offer comments on my own behalf and to present my grave concerns with EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

I'm a fourth generation Southern Californian who lived the first 18 years of my life in Northern Los Angeles County. And while I'm proud to be from the Golden State, it also

means that I grew up breathing some of the worst air pollution in the nation. Despite tremendous improvement, 70 percent of Californians live in an area with unhealthy air. As a result, I also grew to be familiar with the dangers of air pollution and the importance of health-protective regulation.

My family lives in a town that, like much of LA County, is in the United States 98th percentile for tropospheric ozone, according to EPA's own Environment Justice Screen.

Tropospheric ozone, commonly referred to as smog, is the visible layer of air pollution that gives LA sunsets their famous striped hues. Several studies have consistently reported there is a significant association between ozone pollution and premature death. According to the American Lung Association, long-term exposure to ozone pollution is also linked to developmental harm, reproductive harm, cardiovascular harm, and increased susceptibility to infections.

While I never had a snow day before

moving to D.C., like most SoCal kids, I'm very familiar with bad air days. Instead of playing outside and building snowmen, children in Southern California lose all outdoor playtime on bad air days in order to avoid the harmful effects of smog. Coughing, impaired athletic performance, eye irritation, chest pain, nausea, headaches, and respiratory congestion.

Smoggy days can also worse asthma, heart disease, bronchitis, and emphysema.

My sister and I enjoyed the early years of childhood with fewer complications relative to my neighbor peers. But before even starting high school we both had missed days of school for nose bleeds that were likely triggered by the irritating smog that settled in the valley, and because ozone forms by the interaction of sunlight with hydrocarbons and nitrogen oxides emitted from cars and trucks, bad air days tended to worse each year, our Southern California summers, broke standard heat records of years before.

Shortly after my sister joined the high

school soccer team, my family started to notice that her once limitless stamina on the field was wearing down. One particularly hot and hazy day, she had no choice but to walk off the field in the middle of the match. Clutching her chest, she struggled to breath. We later learned that she had developed asthma from LA's unhealthful smog, like many of our friends and family in the area.

It was experiences like this that motivated my decision to study environmental policy in college, and that continued to drive my legal career. Having witnessed first-hand the way in which the geography of where one lives, plays, learns, works, and grows determines one's health outcomes, I could not have chosen another path in good conscience.

When I first chose this path, over eight years ago, my hope was to strengthen the laws and regulations that did not go far enough to protect my family and our environment.

Under the Clean Air Act, EPA was required to establish and regularly update federal

standards for hazardous air pollutants, including asthma-causing particulate matter and ozone. These standards and the National Ambient Air Quality Standards or NAAQS, form the backbone of our nation's air quality protections. Although the NAAQS did not prevent my sister's asthma, they have and continue to bring about substantial improvement in our nation's air quality since their first formulation.

The EPA's proposed rule would have excluded peer review studies that form the scientific basis of NAAQS. For example, peer reviewed studies would be excluded because the underlying data and models cannot be disclosed, even in partial form. In fact, the standards would not have been issued had the proposed rule been in place when they were first enacted in the 1970s, because EPA would have tossed out the underlying studies, tying its hands from taking action in imminent public health concerns.

Without a doubt, many more Southern Californians would have had their lives altered,

or even cut short by dangerous levels of air pollution.

If adopted, the proposed rule would deprive EPA policy makers from real world evidence and studies that are vital to the EPA's review of the NAAQS into the future. Further, the proposal directly contravenes the comprehensive federal and state regulatory program congress envisioned when drafting the Clean Air Act of 1970. It reduces our public health legislation to mere declarations, as EPA would severely delayed if not rendered entirely unable to establish future standards using the best available science.

Generations before me, through legislation like the Clean Air Act, recognize that public health and environmental pollution required strong federal leadership and expert agencies like EPA. Departing from the Agency's practice of scientific review for over the last 40 years, practices aligned with national and intergovernmental bodies, like the Royal Society of Medicine, and the World Health Organization,

jeopardizes EPA's ability to utilize its expertise with high cost to people's health.

It is therefore troubling that the Agency has proposed to take this action under the guise of scientific integrity without consulting its own panel of scientific experts, the Science Advisory Board, and against the advice of leading scientific journals and organizations. It is even more troubling when considering the Agency's recent practices toward the public and the press, which have been far from transparent.

To me, it is clear the proposal's purported goal of transparency is a pretext for the Agency's attempt to shirk its statutory command. For the health of my sister, my friends, and all Americans, I urge EPA to abandon this proposed rule. Thank you.

MR. ROBBINS: Thank you.

MS. XIE: Good morning. My name is Jenny Xie, J-E-N-N-Y, last name X-I-E, and I'm a policy intern at the Environment Defense Fund, but I'm here today speaking from a personal capacity to

express my personal opposition to EPA's proposed rule, "Strengthening Transparency in Regulatory Science."

Many of the activities that I am involved in on campus involve holding the university accountable for its environmental goals that it has set. I'm currently a student at Cornell University, studying English and Environmental Sustainability Sciences.

In fact, one of the main initiatives that I am involved in calls for the University to disclose as a financial investments and fossil fuels in order to increase transparency, have accountability, and maintain integrity as it works towards its carbon neutrality. It is therefore incredibly disheartening to hear that this EPA administration is championing a proposed rule that claims to be for increased transparency, when in fact the purpose and the fact of the proposed would be to bar EPA from considering rigorous public health science and reduce the transparency of EPA's scientific analysis.

The proposed rule would require the EPA base some of its most important regulatory decisions only upon does response studies where the underlying data can be disclosed. The reality is that key scientific studies backing our nation's critical clean air safeguards which protect our health and environment are based on confidential patient data that in many cases cannot be disclosed in any form.

These rigorous peer-reviewed state of the art studies could be improperly discarded should this rule be finalized. As many scientists have noted, this would undermine and not promote the use of sound science in EPA decisions. Just because the data underlying a study isn't published does not mean that the study cannot be verified using other means.

For example, the American Cancer Society's Cancer Prevention Study II, tracked air pollution, exposure, and personal medical histories of nearly 670,000 people for more than two decades to understand the exact risk of air

pollution on death.

The study was based on private patient information that cannot be publicly disclosed, and yet the study has been subject to reanalysis and its conclusions have been upheld. And allowed under the scientific journal does response, the authors listed 16 key studies alone which supported the original conclusion of the Cancer Prevention Study 2.

Even more concerning is the fact that the proposed rule provides the administrator with broad discretion to make exception to the policy on a case-by-case basis. Former Administrator Pruitt may be out of office now, but Acting Administrator Wheeler's record as a fossil fuel lobbyist for corporations like Murray Energy leaves me and others incredibly skeptical that this rule would be applied fairly with no concrete criteria guiding decision to grant an exception.

This part of the proposal raises a serious risk that this or future administrations could selectively waive the policy to build a

distorted scientific record that is designed to reach a desired result. In fact, just a few weeks ago I was in Pennsylvania where I'm from, talking to an Uber driver. He's a father with a daughter who has asthma, and we talked about the EPA. He had worked in public service before and expressed to me how frustrated he was with the current administration, with the EPA, and how it seemed that despite the endless promises the administration has made to protect its citizens and better our lives, many of those promises were not being fulfilled.

I can't help but think how disappointed he would be if he knew that the EPA has proposed a rule which will make it more difficult for EPA to use the best science to protect the health of him and his family. Citizens are watching and aware, from parents, to scientists, to students like me who advocate for good policy on their own college campuses.

The EPA hastily shuttled this rule past even the OMB, but it must pause to hear the

concerns of the public. EPA's proposal will lead to censored science, not transparent science. Thank you for the opportunity to testify on the proposed rule today.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 26, Ann Mesnikoff, and Speaker Number 27, Roy Gamse, come up to the speaker's table. And Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, please take your seat at the on-deck chairs.

MS. MESNIKOFF: Hi. I'm Ann Mesnikoff. It's M-E-S-N-I-K-O-F-F, and A-N-N, no E.

Good morning. I'm Ann Mesnikoff. I'm the Federal Legislative Director for the Environmental Law and Policy Center.

ELPC works throughout the Great Lakes and the Midwest, protecting public health and special places under the belief that environmental protection and economic development can be achieved together.

ELPC appreciates the opportunity to

testify in opposition to EPA's proposal to censor, or otherwise constrain the science it will consider in issuing essential standards that are meant to protect public health and our environment. The Midwest and the Great Lakes region, with its industrial and agricultural heritage is impacted by environmental and public health challenges to air, land, and water, and we depend upon EPA to effectively implement environmental laws to protect the public and our environment.

There is no basis in existing bedrock environmental laws that authorizes EPA to limit science considered in rulemaking processes. EPA cites several key laws in its justification for this proposal. Nowhere in the cited statutes is there a basis for demanding access to raw data, nor does this relate sensibly to any definition of best available science. Rather, this undermines the use of best available science called for in environmental statutes, including the Clean Air Act.

Further, there is no basis for politically appointed administrators to choose which science will be considered, and which may not be. EPA should continue to apply the rigorous standards the Agency has used for decades, and that stakeholders engage in the process that is full and open with regards to science.

EPA's Science Advisory Board voted to review this action during its June 1st meeting. This proposal has also prompted, as we've heard today, vehement reaction from the scientific community. EPA's proposal is not about transparency. It is about undermining public health. The negative effects of this proposed rule on EPA's programs could be far reaching across the Midwest. Midwesterners are exposed to unhealthy levels of air pollutants, including particulates, ozone, and toxic emissions from our industries and agricultural operations.

Achieving and maintaining health air to breath remains a challenge. EPA just finalized not attainment designations for Midwest's biggest

cities. There are millions of people -- where millions of people live, work, and play. Foundational studies about the impact of air pollution to public health are essential. These studies have been reviewed numerous times. Yet, under EPA's proposal, they would be ruled out of bounds, compromising the Agency's ability to truly assess the impacts of air pollution and to set standards are a level that will protect public health as the Clean Air Act requires.

Weaker standards will mean dirtier air in our communities. The elimination of these studies would also skew the evaluation of cost and benefits, leading to less protective rules that will not be based on a true accounting of the public health costs of pollution. We're also concerned about how EPA's proposal to censor science will impact a range of other significant concerns across the Midwest and Great Lakes, from using the best available science and its review of toxic -- the toxic insecticide, chlorpyriphos, the impacts of growing problems of harmful algael

blooms in Lake Erie and other places across the Great Lakes on public health, and in setting standards for lead in water, soil, and in homes.

EPA has shown time and again that achieving cleaner air, and water, and a healthier environment go hand-in-hand with economic growth. Our children's health across the Midwest depends on EPA continuing to do its job and not let industry-driven agenda undermine its essential role. We respectfully ask EPA to withdraw this proposal. We will be submitting more detailed comments to the record. Thank you.

MR. ROBBINS: Thank you.

MR. GAMSE: I am Roy Gam -- I am Roy Gamse, G-A-M-S-E, no S on the end. Formerly EPA Deputy Assistant Administrator. Reading the comments of John Bachmann of the Environmental Protection Network. He served EPA for 33 years, was Associate Director of Science Policy and New Programs for the Office of Air Quality Planning and Standards.

John's comments. "I appreciate the

opportunity to provide the comments on the proposed rulemaking on strengthening transparency on behalf of EPN. EPN will submit the detailed written comments on the proposal later."

"This proposal would not strengthen transparency of regulations. Instead, it would preclude the assessment and use of best scientific information available as required by all major statutes administered by EPA. The process by which it was developed, the misuse of references that ultimately do not support its arguments and the lack of specifics, what EPA actually intends to do are an embarrassment to the agency."

"The new acting administration should withdraw it from consideration as soon as possible. EPA's proposal is a solution in search of a problem. A proposal asserts it's dealing with a replication crisis, but does not cite a single instance where a study used by EPA for any type of major rule was shown to be flawed due to a lack of access to the underlying data. In fact, EPA and the industry funded an independent

reanalysis of the two air pollution studies that were criticized for not releasing confidential health information, and both were successfully reproduced with the results published in 2000. Moreover, their key findings have been replicated dozens of times since then by other investigators using different health and air quality data."

"The proposal to exclude important peer reviewed studies is wholly inconsistent with scientific practice and EPA's past use of science and regulatory decisions, where studies with novel results appear, EPA's assessments have noted limitations and some cases supported reanalysis."

"EPA's science policy related assessments are, themselves, peer-reviewed by the SAB or CASAC to further ensure study evaluations consider all of the relevant scientific literature."

"As noted by the SAB workgroup, the EPA's proposal downplays valid concerns about the risks of providing access to the confidential information of subjects in epidemiology studies. The SAB group noted some of the largest most

useful health effects data sets cannot be made fully public because certain personal information of age, sex, health, and location could be used to identify participants, or because of agreements made with study participants in advance."

"EPA failed to mention various ways to assess the validity of fire epidemiology studies without access to data, nor that the rule may preclude continued use of studies published many years ago."

"The proposal includes a provision for the administrator to waive this requirement. No clear decision criteria provided to allow EPA scientists and stakeholders to understand when and how the waivers would be granted. It appears that requirement could be applied in an arbitrary and capricious manner that does not reflect sound science judgment. Critical decisions like these must be made on the basis of science, not politics. Otherwise, highly relevant studies for which data can't be publicly shared, even if published in the best peer reviewed journals and

replicated may be judged to be inherently untrustworthy."

"The rushed, mostly secret process EPA followed in developing the proposal displays a complete disinterest in transparency, much less in science. In developing this proposal EPA leadership did not provide a role for zone career science experts in crafting the proposal, never included the rule on its regulatory agenda, did not notify of consult with the SAB, much less request the review as required by law. Did not solicit the advice of the NAS on provisions that would change does response models used in risk assessment from those previously recommended by NAS, did not ask for review to solicit the views of other federal agencies that conduct research or use health effect science in developing regulations. Finally, the Agency originally only allowed a 30-day comment period on this remarkable unvetted departure from the past practice."

"In suggesting potential cost of the rule would be minimal, EPA ignored the cost to

researchers who would have to pay to set up and maintain data sharing for their previously published studies to be considered, to EPA for conducting the multiple reanalysis required in Section 30.6 of the rule, and to public health for the disbenefits of undermining existing regulations. Having done no assessment, EPA has no basis for its claim that the benefits of the rule exceed its cost. Scientists and scientific publications that EPA cites as evidence for support for this rule have rejected the proposal's preemption of existing studies based on availability of raw data. Professor John Ioannidis reacted strongly to the proposal in an editorial noting that, quote, 'If the proposed rule is approved, science will be practically eliminated from all decision-making processes. Regulation would then depend uniquely on opinion and whim.' End quote."

"Editors of four major scientific journals whose policies EPA cited as support jointly stated, quote, 'It does not strengthen

policies based on scientific evidence to limit the scientific evidence that can inform them. Excluding relevant studies simply because they don't meet rigid transparency standards will adversely affect decision-making processes.'"

"Finally, EPA should immediately withdraw this flawed proposal from consideration, given the fatal flaw of establishing unnecessary regulation for science assessment that would elevate transparency over any other criterion. We're unable to offer any suggests for improving it."

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 28, Jennifer Sabb (sic), and Speaker Number 29, Paul Miller, come up to the speaker's table. And Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic), take a seat at the on-deck chairs.

Please remember to speak into the mic and state your organization.

MS. SASS: Hello. My name is Jennifer Sass, S-A-S-S. I'm with NRDC, the Natural

Resources Defense Council.

And I'm here to talk about the concern that scientists and environment health and medical professionals have with this rule. In one of his last acts of aggression against the public before resigning, the corrupt and disgraced EPA Administrator Scott Pruitt, proposed the rule to restrict the scientific studies that EPA could rely on to set safety standards for toxic chemicals.

Ironically, the rule is called science transparency when in truth public health will be seriously harmed. That's why over 40 doctors and scientists released a letter today which was submitted to the docket, raising alarm about the rule and the harms that it would bring about.

In the letter, they say as scientists and health professionals we recognize the importance of data sharing and replicability in scientific practice and discourse. The experts are part of Project Tender, and their letter is also publicly available.

They say the proposed rule is about stiffing science used by EPA, not improving it. They all have careers devoted to protecting children and their families from exposures to neurotoxic chemicals. They say the proposal could also undercut existing safeguards. Regulations that have led to protections against toxic air pollution, lead and drinking water, and dangerous pesticides, such as chlorpyrifos.

Dr. Phil Landrigan, a globally renowned expert on childhood harm from chemical pollutants warned that if you implement this proposed rule the inevitable consequence is that chemicals with potential to damage children's brains and nervous systems will remain longer on the market, and many thousands of children born, and not yet born, who could have been protected against these chemicals, will be unnecessarily exposed. Brain damage with loss of intelligence, disruption of behavior, and diminished lifetime achievement will be the result. Is this the legacy that EPA wishes to leave for America's children?

The Economist also wrote about the rule, very bluntly in an article titled, "Swamp science: Scott Pruitt embarks on a campaign to stifle science at the EPA." In that Economist article they emphasized that the proposal rule is really about blocking information used by EPA to protect our health. The rule prohibits the Agency from setting regulations that are supported in part or whole by data that is not publicly available for reanalysis or that cannot be replicated. It will hamstring EPA's use of scientific information, which could only harm EPA's work quality and public credibility.

There are many reasons why a study cannot be made fully public or replicated. For example, the original raw data may no longer be -- exist. Or the original exposure conditions may no longer exist, such as lead exposures from leaded gasoline, and patient protection and privacy rules may prevent full disclosure of the raw data, or information. EPA already has long-established and transparent methods for evaluating data in these

situations.

This rule would block the studies used to set air pollution regulations that will have prevented more than 30,000 premature deaths by 2020, with benefits valued at 30 times the cost of the Clean Air Act, according to EPA scientists and technical experts.

The rule would also block the studies that protect children from lead poisoning in air, water, and soil, and would block the studies of harmed children that support an EPA proposed ban on the neurotoxic pesticide chlorpyrifos, which President Trump and former Administrator Pruitt have already rolled back those proposals.

This may be the most unpopular proposal from an already unpopular EPA administration to date. It is a rule that fundamentally purports to solve a problem that doesn't exist, and it should be abandoned. It cannot be fixed. Thank you.

MR. ROBBINS: Thank you.

MR. MILLER: Hello. My name is Paul Miller. It's M-I-L-L-E-R. I am Deputy Director

of the Northeast States for Coordinated Air Use Management, or NSCAUM. NSCAUM is the regional association of state air agency air quality control agencies in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

My comments today reflect the majority view of NSCAUM's members, while individual members may hold some views different from the majority consensus.

In sum, we are concerned that should this proposal lead EPA to not fully consider the best available science in rulemakings, it will endanger public health and the environment.

The EPA invokes strengthening transparency as a primary driver for this proposal, but fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of work, quote, "EPA has not previously implemented these policies and guidance in a robust and consistent manner," end quote, nor what are the specific

quote, "Agency culture and practices regarding data access," end quote. That requires changing.

The Agency also provides no cost analysis of this proposal. Without additional clarity from EPA we are having difficultly identifying the problem EPA seeks to address. Therefore, for the following reasons we request that EPA withdraw the proposed rule.

First, the proposal is too vague as written to provide the public with meaningful opportunity to comment. EPA solicits comments across a long list of topic areas, but fails to provide the Agency's own sufficient detail and rationale on the solicited comment areas as required by the Administrative Procedure Act.

We are left to speculate on EPA's views, and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment.

Second, EPA must describe how the proposed text in Sections 30.5, 30.7, and 30.9

affect current practice. Section 30.5 states that the Agency shall ensure that those response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation.

Section 30.7 states, EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions. EPA, however, does not describe what constitutes in its view, independent validation and independent peer review.

Furthermore, Section 30.5 includes qualifying language that EPA will take all reasonable efforts to make data available unless it is not possible due to other constraints, such as legal protections of privacy and confidentiality.

EPA provides no examples of where and how, in the Agency's view, past rulemaking specifically failed to make these same efforts, nor how EPA would change past practice in this context. Adding to the vagueness of Sections 30.5

and 30.7, Section 30.9 would provide the administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions on a case-by-case basis if he or she determines that compliance is impracticable. The proposed rule fails to provide specific criteria for determining when compliance is impracticable.

Lacking clear guidelines for transparent decision-making, the administrator's discretion would appear to be unbounded in application and potentially based on haphazard and non-transparent rationales.

Third, EPA has provided no meaningful cost estimate for the proposed rule. The costs are likely quite significant, however, based on a congressional budget office cost estimate of the similar congressional proposal.

In addition to lack of cost information, EPA offers no accounting of foregone benefits should a broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse

health outcomes.

In conclusion, EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific proposed rule requirements, and its cost and benefits.

These are well understood and basic elements that federal agencies must include to ensure informed public comment. Given that these elements are missing from this proposed, EPA should withdraw it. Thank you.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 30, Matthew McKinzie and Speaker Number 31, Anne Mellinger-Bird (sic) come to the speaker's table. Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Reaves, take a seat at the on-deck chair.

MR. McKINZIE: Good morning. I'm Matthew

McKinzie, M-C-K-I-N-Z-I-E. I'm a nuclear physicist with the Natural Resources Defense Council, NRDC, and I'm very pleased to talk today about this proposed rule. My remarks will focus in on the radiation protection aspect of the proposed rule.

NRDC, just as background, is a national non-profit organization of scientists, lawyers, and environmental specialists. We are dedicated to protecting the public health and the environment.

NRDC has been engaged with the environmental issues surrounding nuclear energy and nuclear weapons since our founding. There's something strange about the proposed rule in that it does not use the word radiation, and it does not cite the EPA's authority under the Atomic Energy Act.

Nevertheless, the language of the proposed rule seems to clearly implicate radiation protection standards. In particular, appears to undermine the basis, a fundamental basis of

radiation protection standards, the linear no-threshold dose response model. And so that's what I'll focus on with my five minutes.

The science in radiation epidemiological studies has repeatedly demonstrated over decades that linear no-threshold dose response, LNT, provides the most reasonable description of the relation between the low dose, low radiation dose exposure, and the incidence of solid cancers that are induced by that ionizing radiation.

EPA bases its regulatory limits and nonregulatory guidelines for population exposure to low-level ionizing radiation on this linear no threshold model. EPA's radiation protection standards are based on the premise that any radiation does carries some risk, and that risk increases directly with dose.

This method of estimating risk is called LNT. For over 40 years, the LNT dose response model has been commonly utilized when developing practical and prudent guidance on ways to protect workers and members of the public from the

potential for harmful effects from radiation in that balance, with commercially justified and optimized uses of radiation. EPA derives the LNT model from reports by authoritative scientific bodies, including the National Academy of Sciences, NAS, the National Council on Radiation Protection and Measurements, NCRP, and other bodies.

The NCRP published its last commentary on the LNT issue only weeks ago, in April of 2018, reinforcing this -- the LNT as the basis for radiation protection standards.

Epidemiological studies of humans provide evidence that is critically important in establishing potentially causal associations of environmental factors with disease. NAS and other studies that EPA has long relied upon in the radiation standard setting process are epidemiological human cohort studies. EPA's proposed rule, if implemented, would limit EPA staff from basing regulatory actions on precisely these types of studies by requiring that the

underlying data of these studies should be publicly shared, fully publicly shared. This would be a nearly impossible task for the agency.

Data for some of the radiation epidemiological studies are accessible to users, with a detailed description of how a user can access the information. However, public sharing of personally identifiable information is restricted. These are profoundly important studies on radiation health effects that have been peer reviewed for decades, and the science that has emerged from them has been validated multiple times. But these are not studies where the entirety of the public data can be shared or independently replicated.

Replication of these studies is impossible as this data comes from individuals exposed to significant, acute, and protracted doses of radiation. Pruitt's proposed rule would throw out the data from the atomic bomb survivors of World War II. That's a profound, very profound thing.

Adverse consequences for EPA would affect federal guidance reports, nuclear field cycle standards and regulations, minimum amount -- minimum allowed concentrations of radiation in drinking water, soil clean up for super fund sites, radioactive waste disposals, as well as the fundamental concept of ALARA, As Low As Reasonably Achievable, in radiation protection standards.

In conclusion, I urge the EPA to abandon the proposed rule as it fundamentally calls into question basic radiation protection standards that are scientifically founded and have protected the public for many years. Thank you.

MR. ROBBINS: Thank you.

MS. MELLINGER-BIRDSONG: Hi. My name is Anne Mellinger-Birdsong, M-E-L-L-I-N-G-E-R, dash, B-I-R-D-S-O-N-G.

Thank you for allowing me to speak today. My name is Anne Mellinger-Birdsong, and I am a fellow of the American Academy of Pediatrics and a specialist in environmental public health. I have worked at city, county, state, and federal public

health agencies, and Indian health service facilities.

I'm here to speak in opposition to this proposed rule and to state that this proposed rule is unnecessary and it would harm EPA's ability to evaluate health impacts of environmental pollutants. It should not be finalized or implemented.

This proposal has wording that makes it appear noble and well-meaning, but it is a sheep in wolf's clothing. This proposal will severely hamper EPA's ability to use past and future research on health effects of human exposure to environmental chemicals and toxicants. It should be withdrawn.

Both the HIPAA and the federal regulations on human subjects research address privacy as a concern of people who participate in research. It's not as simple as redacting data such as name, birth date, medical record number, et cetera. You also have to not have data that can be used to intuit or figure out who a study

subject is. So you have a study of Town A and people who had heart attacks in July. If there is age or zip code data associated with that, the people that live in Town A could figure out, oh, that's Mr. X down the street. So it would really hamper the ability to use data, and environmental health data often has zip code and year and a lot of stuff that can be used to put together and figure out who people are.

So that's how it would work. And I just would like to say also that children have even more health protections than adults because of being smaller, and we have to be more concerned for them. And especially living human subjects of research who will continue to live, we need to be extra careful to protect their privacy. And this rule would either require data made public, or it would prohibit using a lot of data that would enable -- that would inhibit privacy protection.

So also it would decrease people's trust in participating in research if they are fearful of their personal identifiers being released or

people being able to know that they participated in a study. They may not participate, so we would have worse data for studies in the future because of this rule.

And I would like to say that children do not choose where they live, or where they go to school, or what kind of water quality their water they drink is, or the air that they breathe. It's up to we, who are adults, the adults who are their caretakers who choose where they live, and we who set policies to make these decisions to keep children healthy. And this rule would severely harm children because it will throw out a lot of data, and a lot of data that has been used to form, already, established rules.

So I ask, why was this rule proposed? It would eliminate use of scientific studies and hamper future research. The rule was completely unnecessary. We have mechanisms within scientific institutions to transfer data so it's HIPAA compliant and IRB approved, so we can verify research and reevaluate it and confirm it. We

don't need this rule and it is, again, it's a rule that's unnecessary and would hamper and harm EPA's ability to carry out its functions.

So I'm going to end with a quote by a professor from Carnegie Mellon University, Granger Morgan. He used to chair the EPA Science Advisory Board under George W. Bush. He said, "this proposed rule is an attempt by people who aren't interested in using science to find the truth to raise doubts about what, at this stage, is very clearly established and well-reviewed science."

And I urge the EPA to withdraw this proposed rule and not implement it at all.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 32, Erica Bardwell, and Speaker Number 33, Jennifer Rebeb (sic), come up to the speaker's table. And Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb, take a seat at the on-deck chairs.

Speakers are reminded to speak into the mic and state your organization.

MS. REAVES: Hi. My name is Jennifer Reaves. Reaves spelled R-E-A, V as in Victor, E-S. I represent Moms Clean Air Force, Maryland.

Am I supposed to speak first? Oh, okay.

My name is Jennifer Reaves. I live in Hyattsville, Maryland. Thank you for this opportunity to offer comment. As a member of Moms Clean Air Force, Maryland, I am here today to speak out in opposition to Acting Administrator Andrew Wheeler's attempts to censor science in the name of transparency.

This dangerous censoring sign plan to limit the scientific information EPA can use to identify public health threatens and future and safety of our children. This proposal will essentially require researchers to make private personal medical information public in order for the EPA to use their research in its decision-making.

This proposal also includes loop holes that would exempt industry from having to disclose details of their own studies. It is designed to

favor the fossil fuel and chemical industries, limiting EPA's ability to protect us from toxic pollution and chemicals. High quality science is crucial to understanding the risk of our families face every day, especially when it comes to air pollution and toxic chemical exposure.

This proposal means that many studies on populations, such as elderly, young people, and people of color, groups who are often suffer disproportionately from pollution would be excluded from EPA consideration because making the data public could identify and participating -- identify the participating individuals. Including this important data from consideration means that implementing this proposal could even further exuberate negative environmental impacts on these and other vulnerable communities.

This proposal puts our children's bodies on the line by censoring research, making even low levels of pollution with significant health impacts instead of cleaning up their act. Polluting industries want these kind of studies to

simply disappear.

My family and my fellow Marylanders are counting on the sound and transparent science the EPA has used for decades. And we are counting on our medical records remaining private. I strongly urge the EPA to stop this radical proposal for the health and safety of all Americans. Thank you.

MR. ROBBINS: Thank you.

MS. BARDWELL: All right. Excuse me. Thank you. My name is Erica Bardwell. Can you hear me? Okay.

I am a local registered nurse. I work at a local hospital. I'm also a member of Physicians for Social Responsibility. Thanks for taking time today.

Mr. Scott Pruitt is no longer here as EPA administrator, but it does seem that this proposal preserves the hallmark of his tenure. By that I have to say, I mean a complete lack of shame.

This proposal masquerades as an attempt to strengthen science, and by extension, public health. But this is a bald, even shameless lie.

It would actually make public health research impossible, or much, much more difficult, which obviously is the real point.

If someone can't participate in medical research without worrying that their identities or parts of their medical records are going to be rampaging around the public record, then they simply won't do it. Which again, is the point.

Basically, shameless people say that to themselves behind their scenes. But to us they say that they're really concerned about us and public transparency, but it's not true.

I saw a reference to a replication crisis. Last I heard, the replication crisis was mostly social sciences. There's not a huge replication crisis in epidemiology. Certainly not to the point where basic facts are in doubt. There is no doubt that air pollution kills people, that poison in water makes people sick, that toxic soil grows toxic food. This is not in contention. There's no replication crisis here.

So the only purpose of this rule could be

to avoid adding to the already damning weight of this existing evidence. Basically, to make it cheaper for a few people to literally poison people for profit, which is ultimately a tragedy for everybody.

I think the thinking is that sciencing debates are going to bore the public, and most other people have to work on a random Tuesday. I swapped a shift to be here, but most people don't have that option.

MS. DOA: Can you speak into the mic a little bit more?

MS. BARDWELL: Sure. Okay.

MS. DOA: That's better. Thank you.

MS. BARDWELL: So, the true public interest may not be represented here because people have to work. But if this rule is finalized, the public is going to howl once they actually feel its effects and lose the protection that they need from these studies. And I wouldn't want to be the person left holding the bag when that travesty happens.

Finally, as my grandmother used to say, what sauce is for the goose is sauce for the gander. If exposing personal information is really required to have quality medical research, I eagerly await the day this administration proposes similar restrictions on, say, pharmaceutical research. I wait for the day that Pfizer can't get approval for its nth blood sugar pill without revealing incredibly invasive information about all of its research subjects. I don't think that day is ever going to come, because protecting people or advancing science isn't really the goal.

Thanks for your time.

MR. ROBBINS: Thank you.

MS. HALL: Would Speaker Number 34, Molly Rauch, and Speaker Number 35, Barbara Gottlieb come to the speaker's table. And Speaker Number 36, Lyndsay Alexander, and Speaker Number -- is there a Speaker Number 37 in the room? What's your name?

MS. BENDER: Laura Bender.

MS. RAUCH: Hi. I'm Molly Rauch. Name is spelled M-O-L-L-Y R-A-U-C-H. I'm Public Health Policy Director with Moms Clean Air Force. We're a national organization of more than a million moms and dads fighting air pollution and climate change for the sake of our children's health.

Thanks for this opportunity to offer comment. On behalf of our more than 1 million members, I am here today to strongly oppose the administration's attempts to censor the science used in public health decision-making. This intentionally misleading proposal is being sold by EPA leadership as an effort to increase transparency. But the facts suggest that the real motivation is simply to sweep under the rug the scientific evidence disfavored by polluting companies.

The proposal would prevent EPA from using studies that are based on personal medical data, thereby eliminating some of the most important long-term epidemiological studies, investigating the impacts of pollution on public health, and

hundreds of scientists have already spoken out against this proposal.

Indeed, this flimsy proposal was designed without adequate input from the scientific community, according to the members of EPA's own Scientific Advisory Board. It was rushed through the regulatory process. It was originally proposed with a gallingly short public comment period that suggested an intention of casting less light on the rulemaking process, not more.

For a proposal that posits a sweeping change in the health-based rulemaking that is the foundation of the EPA, it was quite the slight of hand.

As a public health expert who has been closely following EPA's rulemaking process for more than a decade, it is evident to me that this is a cynical ploy to bolster polluting industries that don't like the results of longitudinal research.

Who does this benefit? Who really benefits from this charade? I must call it a

charade. Not the families everywhere who want to breathe clean air and drink clean water. Not frontline communities dealing with multiple pollution exposures from many industrial sources. Not the millions of children in the U.S. with asthma across the country whose disease can be worsened by small changes in air quality day to day, not the elderly, not those with underlying health problems whose likelihood of being admitted to the hospital, of having a stroke, of having a heart attack, even of dying, could depend on the levels of particulate pollution in the air. It does not benefit these people.

I have a master's degree in public health. One of the most valuable things that I studied in graduate school was how to evaluate the reliability of epidemiological studies. We learn the importance of considering many different criteria in making these evaluations. Whether the raw data was available to me, personally, to review, was never grounds for automatically discounting the credibility or reliability of any

given study.

The idea that an entire library of research would be rejected wholesale, based simply on that one external criteria, represents a crude approach, to put it kindly.

We also, in grad school, learned about the iron-clad importance of treating study subjects ethically and with respect. And this is a touchstone of public health practice. All research on humans must be approved by institutional review boards, and they prioritize the privacy and consent of study subjects. There are laws about this.

When study subjects are disrespected terrible things can happen, which is why we were required to learn about things like the, "Tuskegee Study of Untreated Syphilis in African/American (sic)Men," when we were in public health school. We cannot go back to the time when the study subject was a mere pawn in someone else's game. Treating study subjects ethically requires protecting their privacy.